

REMARKS

By this Amendment, claims 61, 63, and 73 – 77 have been canceled. Claims 58 – 60, 62, 64 – 67, and 70 are amended to more clearly define the invention claimed. New claims 79 – 80 have been added. No new matter is added by these amendments.

Claims 1 – 57 were previously canceled in the Preliminary Amendment filed concurrently with the filing of the current application. Claims 63 – 66 and 78 had previously been withdrawn.

Claims 58 – 60, 62, and 67 – 72, and 79 – 80 are now pending in the application.

The Priority Claim

In the Office Action, the Examiner noted that the current application discloses and claims only subject matter disclosed in prior Application No. 09/741,544, and names an inventor or inventors from that prior application. The Examiner suggested that Applicant amend the first line of the current application to reflect such continuation and/or division status, and/or submit a new declaration from the inventor(s).

Applicant notes that a Preliminary Amendment was concurrently filed with the filing of the current application, with the Preliminary Amendment adding a new first paragraph which noted the continuation status of the current application from Application No. 09/741,544. That Preliminary Amendment is present in the Image File Wrapper of the current application in the USPTO's PAIR system, and is also present in the published version of the current application (namely U.S. Patent Publication No. 2004/0116868).

Applicant also notes that the data filed in Form PTO/SB/05 (Application Transmittal) for the current application reflected the continuation status of the current application. That Form PTO/SB/05 is present in the Image File Wrapper of the current application in the USPTO's PAIR system.

Applicant further notes that the USPTO's PAIR system properly identifies the current application as a continuation of prior Application No. 09/741,544.

In view of the above, no further amendment or documentation is believed required to establish and/or affirm the continuation status of the current application.

The Objection to the Specification

The claims were objected to as varying between the terms “support means” and “supporting means.” By this Amendment, the claims have been amended to substitute the term “stabilizing means” for “support means” and “supporting means.”

The specification was objected to as failing to provide proper antecedent basis for the claimed subject matter. More specifically, the Office alleged that there was no antecedent basis for the claim to “at least one” inner/outer shaft lumen. The objection is respectfully traversed, in that at least one inner shaft lumen and at least one outer shaft lumen are clearly depicted in the drawings and described in the specification. For example, in FIG. 3A, the outer shaft 14 is depicted as having an outer shaft central lumen 44 as well as outer shaft peripheral lumens 46. In FIG. 3B, the inner shaft 12 is depicted as having an inner shaft central lumen 36 as well as inner shaft peripheral lumens 38. See also the respective text in the specification at page 6, lines 12 – 20. Accordingly, there is clear antecedent basis for the claim to “at least one” inner/outer shaft lumen.

The Objection to the Drawings

The drawings were objected to as failing to show “support means.” Applicant believes that numerous examples of “support means” are depicted in the drawings, including the expandable balloons 20 and 24 in FIGS. 2, 4A – 4D, and 5A – 5D, as well as the wire supports 780, 790 in FIGS. 7A – 7C, etc. Applicant notes, however, that by this amendment the term “support means” has been replaced with the term “stabilizing means.” The drawings clearly depict such stabilizing means in the form of balloons and wire supports, and the specification describes the expandable balloons and wire supports as acting to “stabilize the catheter.” See, e.g., page 7, lines 2 – 4; page 11, line 19.

The drawings were further objected to as failing to show “sealing means.” The objection is respectfully traversed, in that numerous instances of “sealing means” are depicted in the drawings and described in the specification. One example is the inflatable balloon 650 depicted in FIG. 6A in the act of sealing an opening in a pericardial membrane 604. The specification (at

page 9, lines 29 – 30) further states, “Pliable inflatable balloon 650 serves to seal the opening created in the pericardial membrane 604, thereby permitting isolated infusion of medicament.” Another example is the balloons 20 and 24 depicted in FIGS. 2 and 4A – 4D. The specification further states, “the balloons act to seal off the passageway in the pericardium made by the inner shaft distal tip.” Accordingly, several example of a sealing means are depicted in the drawings and described in the specification.

The Rejection of Claims under 112

Claim 71 was rejected under 112 on the grounds that the “sealing means” was not described in the specification. The rejection is respectfully traversed in that examples of sealing means are clearly shown and described in the application in sufficient detail to convey its meaning to one of ordinary skill in the art. For example (and as discussed above with respect to the objection to the drawings), FIG. 6A depicts a pliable inflatable balloon 650 sealing an opening in a pericardial membrane 604. The specification (at page 9, lines 29 – 30) further states, “Pliable inflatable balloon 650 serves to seal the opening created in the pericardial membrane 604, thereby permitting isolated infusion of medicament.” Accordingly, the pliable inflatable balloon 650 depicted in FIGS. 6A – 6C is one example of a sealing means.

The Rejection of Claims under 102(b)

Claims were rejected as being anticipated by U.S. Patent No. 6,508,777 to Macoviak et al. By this amendment, claim 58 has been amended to recite that the catheter is configured to permit the first stabilizing means to be moved adjacent to the second stabilizing means in order to hold a tissue wall therebetween. Such a feature is not present in Macoviak et al.

Macoviak et al. teaches a catheter configured to define a space within a body lumen, with the space defined between the balloons, as depicted in, e.g., Fig. 15. In Macoviak et al., the catheter is not configured for use through tissue walls, and is actually configured such that the balloons cannot be brought adjacent “to hold a tissue wall therebetween.” For example, in FIG. 19, of Macoviak et al., the balloons 1996, 1997 cannot be brought adjacent because the balloon 1996 on the outer catheter is spaced away from the distal tip of the outer catheter, including

spacing for a relatively wide radiopaque marker 1976. See, e.g., Fig. 19. Accordingly, the balloons of Macoviak cannot be used to “hold a tissue wall therebetween” as required by claim 58 as amended.

Claims 59, 60, 62, and 67 – 72 depend from claim 58, and are therefore believed allowable in so far as claim 58 is allowable. Moreover, the dependent claims include limitations that further define them over Macoviak et al. For example, claim 67 depends from claim 58 and further recites that the tissue wall is the “pericardial membrane.” It is well known in the art that the pericardial membrane is relatively thin, so that the spacing between the balloons of Macoviak et al. (even if the inner shaft balloon were retracted fully against the tip of the outer shaft) would be too wide to hold a “pericardial membrane” therebetween as required by claim 67. Accordingly, claim 67 is believed allowable over Macoviak et al.

Claims 70 – 72 also depend from claim 58, and include the further limitation of a sealing means configured to seal the opening in the tissue wall. No such teaching or suggestion is present in Macoviak et al., which instead seals off a section of a body lumen. Accordingly, claims 70 – 72 are believed allowable over Macoviak et al.

In view of the above, claims 58 – 60, 62, and 67 – 72 are believed allowable over Macoviak et al.

The New Claims

New claims 79 – 80 recite a catheter for delivering agents to a defined biological space within a patient comprising an inner catheter shaft having a first balloon thereon, an outer catheter shaft having a second balloon adjacent the distal tip thereof, and wherein the catheter is configured so that the first balloon can be moved adjacent the second balloon in order to hold a tissue wall therebetween. Claim 80 adds that the tissue wall is a pericardial membrane.

Such an apparatus is not taught by the cited Macoviak et al. reference, which instead teaches a device wherein the balloons cannot be moved adjacent and which is configured to define a space within a body lumen and between the balloons (as opposed to stabilizing/holding tissue walls between the balloons as in the current invention). Accordingly, new claims 79 – 80 are believed to be allowable.

Fees Due to File This Amendment

Prior to the pending Office Action, a fee was paid for 20 claims, with 3 of them being independent claims. The aforementioned claim additions and cancellations have not resulted in more than the number of total or independent claims originally paid for. No claim fees or other additional fees are believed required for this Amendment, but the Commissioner is hereby authorized to charge any amounts and/or fees required in connection with this Amendment, such as under 37 C.F.R. §§ 1.16 or 1.17, including any petition for extension of time, or to credit any overpayment, to Deposit Account No. 50-1225 (Docket No. CVG-5615CON1).

CONCLUSION

Applicants respectfully submit that the application is now in condition for allowance and, accordingly, solicit an early notice to that effect.

Respectfully submitted,



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